IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	)	**3:09-md-02100-DRH-PMF MDL No. 2100**
This Document Relates to:		
PHILADELPHIA FIREFIGHTERS UNION LOCAL No. 22 HEALTH AND WELFARE FUND, ET AL., on behalf of themselves and all others similarly situated,		**3:09-cv-20071-DRH-PMF**
Plaintiffs, **v.**		
BAYER HEALTHCARE PHARMACEUTICALS INC., ET AL.		
Defendants.		

ORDER

This cause comes before the Court for consideration of Defendant Bayer's motion to dismiss (Doc. 36) Plaintiffs' First Amended Complaint. (Doc. 21). Plaintiffs filed a response to the motion (Doc 39) and Bayer subsequently

filed a reply. (Doc. 40). Oral arguments were heard on July 1, 2010. Upon careful consideration of the parties' arguments, the Court determines that Bayer's motion to dismiss shall be **GRANTED**.

I. INTRODUCTION

Plaintiffs (Philadelphia Firefighters Union Local No. 22 Health and Welfare Fund and American Federation of State, County and Municipal Employees, District Council 47 Health and Welfare Fund), are health and welfare benefit funds that directly or indirectly pay for prescription drugs for their participants and their participants' dependents (health and welfare benefit funds such as Plaintiffs are commonly referred to as third party payors). (Doc. 21 ¶¶ 6-7). Plaintiffs seek to represent a proposed class consisting of "[a]ll third party payors in the United States and its territories that purchased, reimbursed, and/or paid for all or part of the cost of YAZ dispensed pursuant to prescriptions in the United States." (Doc. 21 ¶ 123).

Defendants are Bayer HealthCare Pharmaceuticals, Inc., Bayer Corporation, Bayer HealthCare LLC, and Bayer Schering Pharma AG (collectively "Bayer"). Bayer manufactures and markets the oral contraceptive YAZ.

Plaintiffs contend that Bayer and their associates engaged in (and conspired to engage in) a fraudulent, misleading, and unlawful advertising campaign ("fraudulent advertising campaign") that wrongfully promoted YAZ as safe and effective for unapproved off-label uses and concealed or omitted facts

pertaining to YAZ's safety profile. (See e.g., Doc. 21 ¶¶ 4, 65, 66, 68, 70, 79). Plaintiffs claim that the alleged misrepresentations and omissions in the fraudulent advertising campaign expanded the market for YAZ and falsely inflated the price for YAZ, which in turn caused the Plaintiffs, as third party payors, to pay (and/or reimburse) an excessive price for an excessive amount of YAZ prescriptions. (See Doc. 21 ¶¶ 120, 121).

Plaintiffs have asserted claims under the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute and common law claims for negligence, fraud and misrepresentation, and unjust enrichment. Defendants seek to dismiss the complaint in its entirety for failure to state a claim. (Doc. 36).

II. BACKGROUND

A. Factual Background

YAZ "is a combined hormonal oral contraceptive consisting of estrogen and progestin." (Doc. 21 ¶ 36). The estrogen in YAZ is ethinyl estradiol and the progestin is drospirenone. (Doc. 21 ¶ 37). According to the Complaint, "drospirenone has certain side effects that are different from and more dangerous than the side effects associated with [other progestins]." (Doc. 21¶ 52; see also *id.* ¶ 63). Plaintiffs allege that these side effects include an increase in potassium levels which can result in hyperkalemia, a condition that could eventually lead to heart attack, pulmonary embolism, or stroke. (Doc. 21 ¶¶ 53-54). The Complaint

also alleges that individuals who take YAZ have a "substantially increased risk of gallbladder complications." (Doc. 21 ¶ 56).

The Food and Drug Administration ("FDA") has approved YAZ for the following uses: (1) as an oral contraceptive (doc. 21 ¶ 39); (2) as a treatment for moderate acne vulgaris in women who choose to use an oral contraceptive (doc. 21 ¶ 41); and (3) as a treatment for premenstrual dysphoric disorder ("PMDD") in women who choose to use an oral contraceptive. (Doc. 21 ¶ 40).

"PMDD is a condition associated with severe emotional and physical problems that are closely linked to the menstrual cycle." (Doc. 21 ¶ 44). PMDD and Premenstrual syndrome ("PMS") share some common symptoms, such as depression, anxiety, tension, irritability, and moodiness. (Doc. 21 ¶ 46). The symptoms associated with PMDD, however, are more severe than those associated with PMS. (Doc. 21 ¶ 46). PMDD is estimated to affect 5% of menstruating women. (Doc. 21 ¶ 44). PMS, on the other hand, affects an estimated 75% of menstruating women. (Doc. 21 ¶ 45).

B. Plaintiffs' Claims

Plaintiffs contend that Bayer and its associates[1] engaged in (and conspired to implement and carry out) a fraudulent advertising campaign that

[1] For purposes of Plaintiffs' RICO claims, Plaintiffs allege the existence of two separate enterprises: The YAZ DTC Enterprise and The YAZ Medical Marketing Enterprise (Doc. 21 ¶¶ 137, 155). The YAZ DTC Enterprise is identified as "an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Bayer, including its employees and agents, the marketing firm Young & Rubicam, other

allegedly misled a number of persons or groups of persons, including consumers; patients; physicians; third party payors; pharmacy benefit managers; the medical, pharmaceutical, and scientific communities; and "others involved in the selection, approval, distribution, and payment of the costs for prescription drugs." (See e.g., Doc. 21 ¶¶ 4, 78, 109). The fraudulent advertising campaign allegedly contained misrepresentations regarding the circumstances in which YAZ had been approved for use and YAZ's safety profile. (Doc. 21 ¶¶ 4, 78, 109). Specifically, Plaintiffs allege that YAZ was improperly promoted "as safe and effective for unapproved off-label uses lacking scientific support, including PMS, acne, anxiety, tension, irritability, moodiness, fatigue, headaches, and muscle aches." (Doc. 21 ¶ 68. See also Doc. 21 ¶¶ 68, 87, 97 (asserting that Bayer promoted YAZ as safe and effective for "unapproved off-label" or "off-label" uses); Doc 21 ¶¶ 79, 87, 98 (alleging that Bayer "overstated" YAZ's benefits); Doc 21 ¶ 70 (claiming that consumers selected YAZ over competing drugs and were willing to pay more for YAZ because of its purported "extra benefits")).

In addition, Plaintiffs contend the fraudulent advertising campaign concealed or omitted the following: (1) that the side effects associated with YAZ are different from and more dangerous than the side effects associated with oral

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marketing and publication firms that Bayer associated with to market YAZ directly to patients, and the web designers who created www.YazUS.com." (Doc. 21 ¶ 137). The YAZ Medical Marketing Enterprise is identified as "an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Bayer including its employees and agents, medical education companies, pharmacy chains, and speakers paid by Bayer to promote YAZ for off-label uses at lunches, dinners, videoconferences, CMEs, and other 'educational' programs." (Doc. 21 ¶ 155).

contraceptives that do not contain drospiranone; (2) that YAZ users have a higher risk for adverse events and are at risk of experiencing dangerous life-threatening side effects; (3) and that patients using YAZ should be monitored more regularly than normal while using YAZ. (See Doc. 21 ¶¶ 51-60, 65, 68).

Plaintiffs theorize that the purpose of the fraudulent advertising campaign was to increase profitability by, (1) expanding the market for YAZ and (2) fostering an environment that would allow Bayer to create and sustain a falsely inflated price for YAZ. (See e.g., Doc. 21 ¶ 4 ("[Bayer] conspired with others to implement and carry out" the fraudulent advertising campaign "in order to increase YAZ sales and price YAZ at a substantial but unwarranted premium as compared to safer, equally effective, and cheaper oral contraceptives."); Doc. 21 ¶ 70 ("Bayer expected and intended that such perception would increase consumer demand for YAZ in the form of increased consumption and willingness of consumers to pay more for YAZ than ordinary oral contraceptives in consideration of the purported extra benefits.")).

A key component of Plaintiffs' allegations is that, in addition to oral contraception, YAZ had only been approved for two uses, the treatment of PMDD in women using oral contraceptives and the treatment of moderate acne in women using oral contraceptives. (See Doc. 21 ¶¶ 39-41).[2] Plaintiffs claim Bayer did not want the market for YAZ to be limited to the small subset of oral contraceptive

[2] As noted, the symptoms associated with PMDD and PMS overlap. (Doc. 21 ¶ 46). The distinction being the severity of the symptoms associated with PMDD. (Doc. 21 ¶ 46).

users affected by PMDD or moderate acne. (See Doc. 21 ¶¶ 61, 62, 64, 110).[3] Accordingly, Plaintiffs contend, Bayer decided to promote YAZ as a safe and effective treatment for conditions or symptoms that are estimated to affect a greater number of potential users, namely acne of all severities, PMS, and/or other premenstrual symptoms not severe enough to warrant a diagnosis of PMDD. (See Doc. 21 ¶¶ 61, 62, 64, 65, 74-75, 77-79, 107-110).

The fraudulent advertising campaign was allegedly accomplished using the following mechanisms: producing and sponsoring television commercials that allegedly promoted the drug as safe and effective for off label uses while minimizing risks associated with the drug (Doc. 21 ¶ ¶ 71 – 76); sponsoring a YAZ promoting website which "[falsely] indicat[ed] that all patients with moderate acne were candidates for YAZ and "failed to communicate any safety information" (Doc. 21 ¶ 77); providing financial incentives to pharmacies to draft "Dear Doctor" letters that promoted YAZ as a safe and effective treatment for PMS (Doc. 21 ¶ 103); sponsoring and/or promoting teleconferences, lectures, and continued medical education programs where physicians were given financial and other incentives to speak favorably about YAZ and promote YAZ for off label uses (Doc. 21 ¶¶ 91-97); and providing financial incentives to physicians as "rewards for past high-prescribing and inducements to write future prescriptions for off-label uses of YAZ." (Doc. 21 ¶ 92).

[3] As noted, PMDD affects an estimated 5% of menstruating women while PMS affects an estimated 75% of menstruating women. (Doc. 21 ¶¶ 44, 45).

III. ANALYSIS

A. LEGAL STANDARD

Rule 12(b)(6) permits a motion to dismiss a complaint for failure to state a claim upon which relief can be granted. To state such a claim, the complaint need only contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In order to survive a Rule 12(b)(6) motion to dismiss for failure to state a claim for which relief can be granted, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 (2007). Motions to dismiss are intended only to test the legal sufficiency of the plaintiff's complaint, not to address the claims on their merits; summary judgment motions are the proper vehicles to consider legal arguments and evidence.

Federal Rule of Civil Procedure 9(b) states that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." In order to meet Rule 9(b)'s strictures and survive dismissal, a plaintiff must generally allege the who, what, where, and when of the alleged fraud. *Ackerman v. Northwestern Mut. Life Ins. Co.,* 172 F.3d 467, 469 (7th Cir.1999); *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir.1990); *see also Vicom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 777 (7th Cir.1994).

B. Counts I and II Civil RICO Claims

1. Overview

In Counts I and II of their First Amended Complaint, Plaintiffs are seeking damages under the civil remedies provision of the federal RICO statute (18 U.S.C. § 1964(c)) for injuries that allegedly resulted from Bayer's alleged violations of 18 U.S.C. § 1962. In Count I, Plaintiffs allege that Bayer violated 18 U.S.C. § 1962(c) by committing acts of mail fraud and wire fraud (in violation of 18 U.S.C. § 1341 and 18 U.S.C. § 1343). (Doc. 21 ¶¶ 134-173). Additionally, Plaintiffs allege that Bayer violated section 1962(c) by using interstate facilities to conduct "unlawful activity" (in violation of 18 U.S.C. § 1952). (Doc. 21 ¶¶ 134-173).[4] In Count II, Plaintiffs allege that Bayer violated 18 U.S.C. § 1962(d) by conspiring to violate section1962(c). (Doc. 21 ¶¶ 174-183).[5]

Plaintiffs' allegations pertaining to mail and wire fraud are based on the alleged fraudulent advertising campaign (television commercials, YAZ promoting website, "Dear Doctor" letters, and other promotional or educational events sponsored by Bayer). (See Doc. 21 ¶¶ 69-78, 91-98, 146-149, 163-165; Doc. 39 pp. 11-12). Plaintiffs also generally allege that Bayer used the mails and wires to promote its fraudulent advertising campaign and to receive and

[4] The term "unlawful activity" is defined to include a miscellany of criminal conduct, ranging from the violent (*e.g.*, arson) to the non-violent (*e.g.*, violation of state liquor laws). *See* 18 U.S.C. § 1952(b)(i)(1)-(3). Bribery is specifically enumerated as an "unlawful activity." *See id.* § 1952(b)(i)(2).

[5] Section 1962(d) provides that: "It shall be unlawful for any person to conspire to violate any of the provisions of subsections (a), (b), or (c) of this section."

distribute the proceeds of its fraudulent advertising scheme. (Doc. 21¶¶ 146-149, 163-165).

The activities that are the basis for Plaintiffs' allegations pertaining to use of interstate facilities to conduct "unlawful activity" is not entirely clear. The portions of the Amended Complaint that Plaintiffs reference in support of this claim contain only general conclusory allegations. (Doc. 39 p. 11 citing Doc. 21 ¶¶ 145, 148, 162, and 165). Paragraphs 91 through 104 of Plaintiffs' Amended Complaint, however, contain allegations regarding money and other benefits allegedly conferred on physicians and pharmacy chains to promote off-label uses of YAZ. (Doc. 21 ¶¶ 91-104). Assuming this section of the Amended Complaint sufficiently alleges bribery, a specifically enumerated "unlawful activity" under 18 U.S.C. § 1952(b), these allegations would be the basis for Plaintiffs' "unlawful activity" claims.

2. Standing

Plaintiffs cannot sustain their civil RICO claims unless they have standing. The RICO civil liability provision, 18 U.S.C. § 1964(c), confers standing on "any person injured in his business or property by reason of a violation of section 1962." 18 U.S.C. 1964(c). The Supreme Court has held that the "by reason of" language requires a showing of proximate cause, i.e., a direct relationship between the plaintiff's injury and the defendant's injurious conduct. *See Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992);

RWB Services, LLC v. Hartford Computer Group, Inc., 539 F.3d 681, 686 (7th Cir. 2008). Thus, in order to have standing, Plaintiffs must show a direct relationship between their alleged injury (paying too much for too many YAZ prescriptions) and the alleged RICO violation(s) (the alleged fraudulent advertising scheme and/or the alleged acts of bribery).[6]

As is explained fully below, the Court finds that Plaintiffs cannot meet the direct relationship requirement. Accordingly, Plaintiffs do not have standing to bring a civil RICO cause of action. Absent standing, Plaintiffs cannot sustain their civil RICO claims and therefore, Counts I and II cannot survive Bayer's motion to dismiss.

3. RICO's Proximate Cause Requirement

In *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), the Supreme Court concluded that the "by reason of" language in 18 U.S.C. § 1964(c) requires a showing that the defendant's violation not only was the "but-for" cause of the plaintiff's injury, but the proximate cause as well. *See Id.* at 267-268. In so holding, the Court explained that it used the term "'proximate cause' to label generically the judicial tools used to limit a person's responsibility for the consequences of that person's own acts." *Id.* at 268. As set forth in *Holmes*, in a civil RICO action, proximate cause is determined by

[6] For the purpose of its proximate cause analysis, the Court assumes that Plaintiffs have sufficiently alleged an "injury to business or property." The Court also assumes that the alleged wrongful conduct constitutes a violation of section 1962.

examining whether a direct relationship exists between the injury asserted and the injurious conduct alleged. *See Id*. at 268-269 (describing the interpretation federal courts had given to the term in the past and holding that the same interpretation applies to section 1964(c) the Court stated that "a plaintiff who complain[s] of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts [is] generally said to stand at too remote a distance to recover." *Id. See also Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006) ("When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries.").

The Court in *Holmes* discussed three policy considerations for requiring a direct relationship between the alleged harm and the alleged injurious conduct:

> First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

Holmes, 503 U.S. at 269-270 (internal citations omitted).

4. Direct Proximate Causation and Third Party Payor Actions Involving Prescription Drugs

a. Controlling Authority

Neither the Supreme Court nor the Seventh Circuit has addressed whether, in the prescription drug context, the claims of third party payors are too remote to satisfy civil RICO's direct proximate cause requirement. The Seventh Circuit addressed claims of a similar nature in *International Broth. of Teamsters, Local 734 Health and Welfare Trust Fund v. Philip Morris Inc.* ("*Teamsters*"), 196 F.3d 818 (7th Cir.1999). Extrapolating from *Teamsters*, however, is difficult because certain aspects of the case are unique to tobacco litigation and clearly distinguishable from the claims advanced here.[7] Nonetheless, because the claims presented in *Teamsters* are at least in the same genre as the claims presented here, a brief review of the Court of Appeals decision for any relevant material is warranted.

In *Teamsters*, welfare benefits funds and health insurers ("insurers") brought civil RICO claims against cigarette manufacturers for costs incurred in the provision of health care services to insured cigarette smokers. The claimed "racketeering acts" involved alleged misrepresentations by tobacco entities regarding the relation between smoking and health that were made to the public in general. *Id.* at 826. The insurers alleged that the misstatements influenced smokers and that they were injured by the amount they paid to provide medical care for smokers afflicted by lung cancer, heart disease, and other ailments.

[7] The Court notes that in light of the Supreme Court's decision in *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008), to the extent (if any) the Seventh Circuit's decision stands for the proposition that first party reliance is required to sustain a RICO claim it has been overturned.

The Court of Appeals concluded that the plaintiffs' RICO claims "flunk[ed] *Holmes*." *Id.* at 825. In reaching its decision, the Seventh Circuit stated: "The injury for which the plaintiffs seek compensation is remote indeed, the chain of causation long, the risk of double recovery palpable because smokers can file their own RICO suits, and the damages wickedly hard to calculate." *Id*. at 825. The Court of Appeals went on to articulate two reasons for deciding that the alleged injury was indirect. First, the alleged misstatements were directed at the public in general and affected the plaintiffs "(if at all) only because they may have influenced smokers." The insurers, the Seventh Circuit reasoned, were reacting to the medical results of smoking and not to the alleged misstatements. Second, the insurers were not seeking to recover money paid to the alleged wrongdoers; rather, they sought recovery of money paid to physicians and hospitals who treated the smokers without committing any wrong.

The Seventh Circuit also summarily rejected the contention that the insurers had been deceived by the alleged misstatements and as a result did not counsel their insureds about the dangers of smoking, which led to higher health expenses. The Court of Appeals explained that "[o]f all entities in society, insurers have the *best* information about the relation between smoking and health problems." *Id.* at 826. (emphasis in original). Further, the Court of Appeals found that attempting to determine what the insurers *would* have done and how effective such a campaign *would* have been was "hopelessly speculative." *Id*.

b. Persuasive Authority

A number of other district courts have considered third party payor civil RICO claims in class actions involving pharmaceutical products. Plaintiffs bringing these claims have encountered a number of difficulties including their ability to meet the direct proximate cause requirement established in *Holmes*. A majority of courts considering the issue have concluded that the injury for which third party payors seek reimbursement is too remote and speculative to maintain a RICO claim. For instance, in *Ironworkers Local Union No. 68 v. Astrazeneca Pharmaceuticals LP, et al.*(Astrazeneca), 585 F.Supp.2d 1339 (M.D. Fla., Nov. 4, 2008), the defendant pharmaceutical manufacturer argued that the third party payor plaintiffs could not establish the requisite causal connection between the alleged RICO violation and plaintiffs' alleged injuries. Relying on the first *Holmes* policy consideration, Chief Judge Anne Conway of the Middle District of Florida, held that the third party payor plaintiffs' alleged injuries were too remote from the alleged misrepresentations to establish direct proximate cause. *Id*. at 1344. Judge Conway explained that it would be difficult to ascertain "damages caused by Defendants' alleged fraudulent conduct, as opposed to damages caused by other, independent, factors." *Id*. According to the district court, the "key independent factor" was that plan participants could only obtain the subject drug with a prescription. *Id.* The district court explained that physicians use independent medical judgment to decide whether to prescribe the subject drug to

a particular patient and that judgment can be influenced by any number of factors. *Id.* Accordingly, establishing that the third party payors' injuries were caused by the alleged misconduct would require an inquiry into each doctor patient relationship to determine whether the physician was influenced by the alleged misrepresentations and to what extent. *Id*.

Similar decisions were reached by other district courts in the following cases: *Southeast Laborers Health and Welfare Fund v. Bayer Corp*., 655 F. Supp. 2d 1270, 1278-12 (S.D. Fla. Jul 30, 2009) (third party payors could not establish proximate cause in civil RICO action against prescription drug manufacturer); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action,* 2009 WL 2043604, at 26 (D.N.J., Jul. 10, 2009) (dismissing third party payors' RICO claims in class action complaint alleging illegal or off-label promotion of prescription drugs where the "court or jury would have to determine whether each prescribing physician received fraudulent marketing information from the Defendants and whether each physician was influenced to prescribe the Subject Drugs on account of Schering's conduct"); *In re Actimmune Marketing Litigation*, In re Actimmune Mktg. Litig., 614 F. Supp.2d 1037 (N.D. Cal. Apr. 28, 2009) (recognizing that doctors prescribe drugs based on "personalized conditions," while rejecting the plaintiffs' claims on causation grounds); *District 1199P Health and Welfare Plan v. Janssen, L.P.,* 2008 WL 5413105, at *9 (D.N.J. Dec. 23, 2008) (questioning whether third party payors "could ever properly plead proximate causation, as required by [*Holmes*] or if the

independent and individualized decision-making of physicians prescribing [the subject drug] breaks any chain of causation between Defendants' alleged misconduct and Plaintiffs' payment for the medication").

5. Direct Proximate Causation in this Case

Applying the proximate cause analysis of *Holmes* and its progeny, this Court is inclined to agree with other district courts that have found direct proximate cause lacking in cases of this nature.[8] In the instant case, multiple steps separate the alleged wrongful conduct (the fraudulent advertising campaign and/or the alleged bribery) and the alleged injuries (paying "too much" for "too many") YAZ prescriptions, including patient preference, the independent judgment of the prescribing physician, and the reimbursement decision rendered by the third party payor and its benefits manager.[9] Thus, the causal link

[8] Bayer contends that Plaintiffs' price inflation theory is a fraud on the market theory of causation and not a proper basis for recovery in RICO cases. (Doc. 36 pp. 3-4). Plaintiffs contend that they are not attempting to invoke the fraud on the market doctrine. (Doc. 39 pp. 9-10). The Court agrees that the fraud on the market doctrine is limited to securities fraud cases and would not be appropriate in a RICO case involving the prescription drug market. However, it is not clear that Plaintiffs are in fact attempting to invoke the fraud on the market doctrine. More importantly, the Court feels assessing whether Plaintiffs are attempting to invoke the fraud on the market doctrine unnecessarily complicates the task at hand. In the instant case, the central question is whether there is a sufficiently direct relationship between Plaintiffs' alleged injury (paying too much for too many YAZ prescriptions) and the alleged wrongful conduct.

[9] Plaintiffs allege and the Court agrees that the presence of multiple victims does not necessarily foreclose a finding of proximate cause. (*See* Doc. 39 p. 6). Plaintiffs' argument is flawed, however, to the extent it asserts that the role of the prescribing physician constitutes the presence of multiple victims. (*See* Doc. 39 p. 6). The role of the prescribing physician is problematic because it is an

necessarily involves the decision making process of the patient, the prescribing physician, and the third party payor. This demonstrates the attenuation in Plaintiffs' civil RICO claims.

Further, the attenuated connection between the alleged RICO violations and Plaintiffs' alleged injury presents serious questions with regard to the ascertainment of damages. To assess damages, the Court would have to delve into the specifics of each physician patient relationship to determine what damages were caused by Bayer's alleged fraudulent conduct, as opposed to what damages were caused by the physician's independent medical judgment. After all, a physician is permitted to use prescription medication to treat conditions other than those stated on the labeling approved by the FDA when, in his or her best medical judgment, use of the drug will benefit the patient. *Piazza v. Myers*, 33 Phila.Co. Rptr. 144, 148 (Pa.C.P. Philadelphia Co. 1997); *see also In re Orthopedic Bone Screw Products Liability Litigation, MDL No*. 1014, 1996 WL 107556, at *3 (E.D.Pa. Mar. 8, 1996) ("the decision whether or not to use a drug for an off-label purpose is a matter of medical judgment, not of regulatory approval") (citation and quotation marks omitted). *See also Leibowitz v. Ortho Pharmaceutical Corporation*, 224 Pa.Super. 418, 431 (1973) ("[i]t is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature,

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additional factor that could have contributed to the Plaintiffs' alleged injury (demonstrating remoteness) and because it confounds the damages analysis (a significant policy consideration raised in *Holmes*).

and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug."). As an example, for some patients, the decision to prescribe YAZ may have simply been the result of the prescribing physician concluding that a drug approved to treat the severe symptoms of PMDD might also benefit a patient presenting with the similar but less severe symptoms of PMS. Attempting to ascertain damages in this scenario, would result in the type of speculative damages analysis the direct proximate cause requirement is intended to prevent. *See Anza*, 547 U.S. at 460 ("The element of proximate causation recognized in Holmes is meant to prevent these types of intricate, uncertain inquiries from overrunning RICO litigation.").

Plaintiffs' contentions with regard to foreseeability and intent do not alter the Court's proximate cause analysis. (*See e.g.*, Doc. 39 p.6 ("Here, victims like the plaintiff funds were not merely foreseeable, but were the intended and inevitable targets of defendants' schemes.")).[10] Plaintiffs' argument on this point goes astray. Bayer's alleged motive does not provide a basis for subjecting it to liability for remote injuries. See *Id*. at 460 ("RICO plaintiff cannot circumvent the proximate-cause requirement simply by claiming that the defendant's aim was to increase market share at a competitor's expense"). Additionally, the Supreme Court's recent decision in *Hemi Group, LLC v. City of New York, N.Y.*, 130 S. Ct.

[10] Plaintiffs also allege that a direct relationship exists because, unlike plaintiffs in civil RICO actions involving the tobacco industry, they are seeking recovery of money paid to the alleged wrongdoer and not an innocent third party. (Doc. 39 p.5 n.2). This distinction, however, does not establish a direct relationship; other factors, such as the independent medical judgment of the prescribing physician, overwhelmingly demonstrate that the alleged injury is not sufficiently direct.

983 (2010), raises questions with regard to the role of foreseeability in a civil RICO proximate cause analysis.[11] Most importantly, the Supreme Court has consistently held that the cornerstone of the Court's proximate cause analysis should be whether the alleged violation led directly to Plaintiffs' alleged injuries. ("[w]hen a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries)" *See Anza*, 547 U.S. at 461. In light of the above, the Court will not stray from the direct relationship test by considering issues of foreseeability and intent. In the instant case, the remoteness of the injury and the speculative nature of any potential damages analysis prevent Plaintiffs from meeting the direct causal relationship requirement and proximate cause is therefore lacking.

One final argument raised by Plaintiffs with regard to proximate causation warrants review. At oral argument, Plaintiffs asserted that if they had been aware of the alleged misrepresentations they would have minimized the number of YAZ prescriptions purchased or reimbursed (presumably by altering their formulary to exclude or restrict coverage for YAZ or through participant

[11]In *Hemi* the plurality criticized the dissent for basing its proximate cause analysis on foreseeability and intended consequences. See *Hemi*, 130 S.Ct. at 991 ("The dissent would have RICO's proximate cause requirement turn on foreseeability, rather than on the existence of a sufficiently "direct relationship" between the fraud and the harm."). *See also Id.* ("Our precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm. Indeed, *Anza* and *Holmes* never even mention the concept of foreseeability."). This portion of the Court's proximate cause analysis, however, rests on a functional plurality (with Justice Gingsberg joining in the Court's opinion and the judgment but declining to endorse the proximate cause analysis of either the dissent or the majority).

education), this argument is no different than the argument raised by the Plaintiffs and rejected by the Seventh Circuit in *Teamsters*. 196 F.3d at 826. In the instant case, attempting to determine what the Plaintiffs *would* have done and how effective patient education *would* have been is "hopelessly speculative" and militates against finding that the alleged injury is sufficiently direct. *See Teamsters*, 196 F.3d at 826.

Considering the intricate damages analysis presented by this case and the remoteness of the alleged injury, the Court finds that Plaintiffs cannot meet the direct proximate cause requirement; therefore, Plaintiffs cannot sustain their RICO claims.

C. Counts III-V Common Law Claims[12]

Plaintiffs have brought common law claims for negligence, fraud and misrepresentation, and unjust enrichment. In order to prevail on the common law claims of negligence and fraud or misrepresentation, there must be a causal connection between the wrongful conduct and the plaintiff's injury. *See MIIX Insurance Co. v. Epstein*, 937 A.2d 469 (Pa. Super., 2007) ("an admittedly negligent act does not necessarily entail liability; rather even when it is established that the defendant breached some duty of care owed the defendant, *it is incumbent upon a plaintiff to establish a causal connection between*

[12] The class certification issue has not been addressed in this case. Accordingly, the Court considers Plaintiffs' common law claims pursuant to the law of Pennsylvania, the state in which the representative Plaintiffs reside. (Doc. 21 ¶¶ 6-7).

defendant's conduct and the plaintiff's injury.) (emphasis in original) citing *Hamil v. Bashline*, 392 A. 2d 1280, 1284 (1978)); *Wilson v. Donegal Mut. Ins. Co.* , 598 A.2d 1310, 1316 (Pa. Super., 1991) (proximate cause is an essential element of a cause of action for fraud or deceit); *Petrucelli v. Bohringer and Ratzinger*, 46 F.3d 1298 (3d Cir. 1995) (to prevail on a claim of fraudulent misrepresentation, the plaintiff must prove a causal connection between the representations and the alleged harm). Further, the proximate cause analysis for Plaintiffs' common law actions mirrors the direct proximate cause analysis applicable in civil RICO actions. *See e.g., Alumni Ass'n, Delta Zeta Zeta of Lambda Chi Alpha Fraternity v. Sullivan 369 Pa.Super.* 596, 601-602 (Pa.Super.,1987)

> [T]he question of foreseeability is not to be confused with the question of legal or proximate causation. Even where harm to a particular plaintiff may be reasonably foreseeable from the defendant's conduct, and that conduct is the cause-in-fact of the plaintiff's harm, the law makes a determination that, at some point along the causal chain, liability will be limited. The term "proximate cause", or "legal cause" is applied by courts to those considerations which limit liability, even where the fact of causation can be demonstrated. Because of convenience, public policy, or a rough sense of justice, the law arbitrarily declines to trace a series of events beyond a certain point, as no longer a "proximate" or "legal" consequence naturally flowing from the wrong-doer's misconduct. To put it simply, at a certain point, negligent conduct will be viewed as too remote from the harm arising to the plaintiff, and thus not a substantial factor in bringing about the plaintiff's harm.

Accordingly, for the reasons already discussed, Plaintiffs cannot establish proximate causation and their claims for negligence and misrepresentation must be dismissed.

As to Plaintiffs' unjust enrichment claim, Plaintiffs must show: (1) Bayer received a benefit; (2) Bayer appreciated the benefit; and (3) Bayer's retention of the benefit without payment of value would be inequitable or unjust. *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 447 (3d Cir.2000) (applying Pennsylvania law). Unjust enrichment may be predicated on either quasi-contract or tort. In the present case, Plaintiffs base their unjust enrichment claim on a tort theory, specifically; Plaintiffs allege that Bayer "represented YAZ in a false and misleading manner." (Doc. 21 ¶ 208). The Court has concluded that Plaintiffs cannot maintain their common law tort claim for fraud or misrepresentation. Accordingly, Plaintiffs' unjust enrichment claim, which is based on this tort theory, fails as a matter of law. *See Allegheny Gen. Hosp.*, 228 F.3d at 446-447 (applying Pennsylvania law and noting that "[t]here is no justification for permitting plaintiffs to proceed on their unjust enrichment claim once it is determined that the District Court properly dismissed the traditional tort claims.") (internal citation omitted).

IV. CONCLUSION

For the foregoing reasons the Court **GRANTS** Bayer's Motion to Dismiss (Doc. 36).

IT IS SO ORDERED.

/s/ David R Herndon

Chief Judge
United States District

Date: August 5, 2010